

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to:

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

On 11/10/06

TOWNSEND and TOWNSEND and CREW LLP

By: Pamela Skelton
Pamela Skelton



PATENT
Attorney Docket No.: 021819-000130US
Client Ref. No. JUV2879.54-3

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Steven W. Dow, et al.

Application No.: 10/780,114

Filed: February 17, 2004

For: SYSTEMIC IMMUNE
ACTIVATION METHOD USING
NUCLEIC ACID-LIPID COMPLEXES

Customer No.: 20350

Confirmation No.: 8036

Examiner: Anne Marie Sabrina Wehbe

Art Unit: 1633

SUPPLEMENTAL INFORMATION
DISCLOSURE STATEMENT UNDER
37 CFR §1.97 and §1.98

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The references cited on attached forms PTO/SB/08A and PTO/SB/08B are being called to the attention of the Examiner. Copies of references BV-BZ and CS-DJ are enclosed. In accordance with 37 CFR §1.98(d), copies of references BO-BQ, BT-BU and CA-CR can be found in Application No. 09/104,759, filed June 25, 1998, now issued U.S. Patent No. 6,693,086 (Attorney Docket No. 021819-000100US).

It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

As provided for by 37 CFR §1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted or that this statement encompasses all the possible relevant information.

Applicant believes that no fee is required for submission of this statement, because this submission is prior to the issuance of a first Office Action on the merits.

However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430. Please deduct any additional fees from, or credit any overpayment to, the above-noted Deposit Account.

Respectfully submitted,


Karen B. Dow
Reg. No. 29,684

TOWNSEND and TOWNSEND and CREW LLP
Two Embarcadero Center, Eighth Floor
San Francisco, California 94111-3834
Tel: 858-350-6100
Fax: 415-576-0300
KBD:tsp
60913832 v1



Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet **1** of **6****Complete if Known**

Application Number	10/780,114
Filing Date	February 17, 2004
First Named Inventor	Dow, Steve W.
Art Unit	1633
Examiner Name	Anne Marie Sabrina Wehbe
Attorney Docket Number	021819-000130US

U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number Kind Code ² (if known)			
	AA	US-4,957,735	09/18/1990	Huang	
	AB	US-5,013,556	05/07/1991	Woodle, et al.	
	AC	US-5,043,164	08/27/1991	Huang, et al.	
	AD	US-5,399,346	03/21/1995	Anderson, et al.	
	AE	US-5,580,859	12/03/1996	Felgner, et al.	
	AF	US-5,589,466	12/31/1996	Felgner, et al.	
	AG	US-5,593,972	01/41/1997	Weiner, et al.	
	AH	US-5,641,662	06/24/1997	Debs, et al.	
	AI	US-5,643,578	07/01/1997	Robinson, et al.	
	AJ	US-5,663,153	09/02/1997	Hutcherson, et al.	
	AK	US-5,676,954	10/14/1997	Brigham	
	AL	US-5,679,647	10/21/1997	Carson, et al.	
	AM	US-5,686,101	11/11/1997	Tagawa, et al.	
	AN	US-5,693,622	12/02/1997	Wolff, et al.	
	AO	US-5,703,055	12/30/1997	Felgner, et al.	
	AP	US-5,703,057	12/30/1997	Johnston et al.	
	AQ	US-5,705,187	01/06/1998	Unger	
	AR	US-5,705,385	01/06/1998	Bally, et al.	
	AS	US-5,723,335	03/03/1998	Hutcherson, et al.	
	AT	US-5,817,856	10/06/1998	Tirosh, et al.	
	AU	US-5,820,873	10/13/1998	Choi, et al.	
	AV	US-5,827,703	10/27/1998	Debs, et al.	
	AW	US-5,830,878	11/03/1998	Gorman, et al.	
	AX	US-5,976,567	11/02/1999	Wheeler, et al.	
	AY	US-5,981,501	11/09/1999	Wheeler, et al.	
	AZ	US-6,121,247	09/19/2000	Huang, et al.	
	BA	US-6,194,388 B1	02/27/2001	Krieg, et al.	
	BB	US-6,207,646 B1	03/27/2001	Krieg, et al.	
	BC	US-6,224,901 B1	05/01/2001	Li, et al.	
	BD	US-6,239,116 B1	05/29/2001	Krieg, et al.	
	BE	US-6,287,591 B1	09/11/2001	Semple, et al.	
	BF	US-6,339,068 B1	01/15/2002	Krieg, et al.	
	BG	US-6,406,705 B1	06/18/2002	Davis, et al.	
	BH	US-6,534,484 B1	03/18/2003	Wheeler, et al.	
	BI	US-6,589,940	07/2003	Raz, et al.	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>			Complete if Known		
			Application Number	10/780,114	
			Filing Date	February 17, 2004	
			First Named Inventor	Dow, Steve W.	
			Art Unit	1633	
			Examiner Name	Anne Marie Sabrina Wehbe	
Sheet	2	of	6	Attorney Docket Number	021819-000130US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number Number Kind Code ² (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	BJ	US-6,627,615 B1	09/30/2003	Debs, et al.	
	BK	US-US2002/0110586 A1	08/15/2002	Madden, et al.	
	BL	US-US2002/0119990 A1	08/29/2002	Madden, et al.	
	BM	US-US2003/0082228 A1	05/01/2003	Flowers, et al.	
	BN	US-			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Country Code ³	Number ⁴	Kind Code ⁵ (if known)				
	BO	PCT	WO94/04196	A1	03/03/1994	Imperial Cancer Research Technology Limited		<input type="checkbox"/>
	BP	PCT	WO93/25673	A1	12/23/1993	The Regents of the University of California		<input type="checkbox"/>
	BQ	EP	0819758	A2	01/21/1998	James Archibald Mixson		<input type="checkbox"/>
	BR							<input type="checkbox"/>
	BS							<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² Kind Codes of U.S. Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/780,114
				Filing Date	February 17, 2004
				First Named Inventor	Dow, Steve W.
				Art Unit	1633
				Examiner Name	Anne Marie Sabrina. Wehbe
Sheet	3	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	BT	VERMA, Inder M., et al. "Gene Therapy - promises, problems and prospects", <i>Nature</i> (1997) 389:239-242	<input type="checkbox"/>
	BU	ORKIN, Stuart H., et al. "Report and Recommendation of the Panel to Assess the NIH Investment in Research on Gene Therapy", (1995) 1-41	<input type="checkbox"/>
	BV	RAZ, E., et al. "Cationic Lipids Inhibit Intradermal Genetic Vaccination", <i>Vaccines</i> (1994) 94:71-75	<input type="checkbox"/>
	BW	GAO, Xiang "Cationic Lipid-Based Gene Delivery: An Update", (undated) pp 99-112	<input type="checkbox"/>
	BX	RODMAN, David M., et al. "Delivery of Genes Through the Lung Circulation", (undated) Chapter 9, pp. 181-191	<input type="checkbox"/>
	BY	FREIMARK, Bruce D., et al. "Cationic Lipids Enhance Cytokine and Cell Influx Levels in the Lung Following Administration of Plasmid: Cationic Lipid Complexes", <i>J. Immunology</i> (1998) 160:4580-4586	<input type="checkbox"/>
	BZ	YAMAMOTO, Toshiko, et al. "Lipofection of Synthetic Oligodeoxyribonucleotide Having a Palindromic Sequence of AACGTT to Murine Splenocytes Enhances Interferon Production and Natural Killer Activity", <i>Microbiol. Immunol.</i> (1994) 38(10):831-836	<input type="checkbox"/>
	CA	BALLAS, Zuhair K., et al. "Induction of NK Activity in Murine and Human Cells by CpG Motifs in Oligodeoxynucleotides and Bacterial DNA", <i>Journal of Immunology</i> (1996) 157:1840-1845	<input type="checkbox"/>
	CB	KRIEG, Arthur M. "Lymphocyte activation by CpG dinucleotide motifs in prokaryotic DNA", <i>Trends in Microbiology</i> (1996) 4(2):73-77	<input type="checkbox"/>
	CC	PISETSKY, David S. "The Immunologic Properties of DNA", <i>The Journal of Immunology</i> (1996) 156:421-423	<input type="checkbox"/>
	CD	SATO, Yukio, et al. "Immunostimulatory DNA Sequences Necessary for Effective Intradermal Gene Immunization", <i>Science</i> (1996) 273:352-354	<input type="checkbox"/>
	CE	STACEY, Katryn J., et al. "Macrophages Ingest and Are Activated by Bacterial DNA", <i>The Journal of Immunology</i> (1996) 157:2116-2122	<input type="checkbox"/>
Examiner Signature			Date Considered

* EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/780,114
				Filing Date	February 17, 2004
				First Named Inventor	Dow, Steve W.
				Art Unit	1633
				Examiner Name	Anne Marie Sabrina. Wehbe
Sheet	4	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²	
	CF	SUN, Siquan, et al. "Dual Function of Drosophila Cells as APCs for Native CD8 ⁺ TCells: Implications for Tumor Immunotherapy", <i>Immunity</i> (1996) 4:555-564	<input type="checkbox"/>	
	CG	LIU, Yong, et al. "Factors influencing the efficiency of cationic liposome-mediated intravenous gene delivery", <i>Nature Biotechnology</i> (1997) 15:167-173	<input type="checkbox"/>	
	CH	LEITNER, Wolfgang W., et al. "DNA and RNA-based vaccines: principles, progress and prospects" <i>Vaccine</i> (2000) 18:765-777	<input type="checkbox"/>	
	CI	LESOON-WOOD, Leslie A., et al. "Systemic Gene Therapy with p53 Reduces Growth and Metastases of a Malignant Human Breast Cancer in Nude Mice", <i>Human Gene Therapy</i> (1995) 6:395-405	<input type="checkbox"/>	
	CJ	OKAMOTO, T., et al. <i>Proceedings of the American Association for Cancer Research</i> (1997) 38: Abstract #78	<input type="checkbox"/>	
	CK	LI, Xiu-Min, et al. "Mucosal IFN- λ Gene Transfer Inhibits Pulmonary Allergic Responses in Mice", <i>The Journal of Immunology</i> (1996) 157:3216-3219	<input type="checkbox"/>	
	CL	McLEAN, John W., et al. "Organ-specific endothelial cell uptake of cationic liposome-DNA complexes in mice", <i>American Journal of Physiology</i> (1997) 273:H3878-H404	<input type="checkbox"/>	
	CM	PISETSKY, David S. "Immune Activation by Bacterial DNA: A New Genetic Code", <i>Immunity</i> (1996) 5:303-310	<input type="checkbox"/>	
	CN	ROMAN, Mark, et al. "Immunostimulatory DNA sequences function as T helper -1- promoting adjuvants", <i>Nature Medicine</i> (1997) 3(8):849-854	<input type="checkbox"/>	
	CO	ROSENBERG, Steven A., et al. "Regression of Established Pulmonary Metastases and Subcutaneous Tumor Mediated by the Systemic Administration of High-dose Recombinant Interleukin 2", <i>J. Exp. Med.</i> (1985) 161:1169-1188	<input type="checkbox"/>	
	CP	SCHEULE, Ronald K., et al. "Basis of Pulmonary Toxicity Associated with Cationic Lipid-Mediated Gene Transfer to the Mammalian Lung", <i>Human Gene Therapy</i> (1997) 8:689-707	<input type="checkbox"/>	
	CQ	TEMPLETON, Nancy S., et al. "Improved DNA: liposome complexes for increased systemic delivery and gene expression", <i>Nature Biotechnology</i> (1997) 15:647-652	<input type="checkbox"/>	
Examiner Signature				Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/780,114
				Filing Date	February 17, 2004
				First Named Inventor	Dow, Steve W.
				Art Unit	1633
				Examiner Name	Anne Marie Sabrina. Wehbe
Sheet	5	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	CR	GREGORIADIS, Gregory, et al. "Liposome-mediated DNA vaccination", <i>FEBS Letters</i> (1997) 402:107-110	<input type="checkbox"/>
	CS	NAITOH, J., et al. <i>Proceedings of the American Association for Cancer Research</i> (1998) 39: Abstract #2421	<input type="checkbox"/>
	CT	HO, Rodney J.Y., et al. "Interactions of Target-sensitive Immunoliposomes with Herpes Simplex Virus", <i>Journal of Biological Chemistry</i> (1987) 262(29):13979-13984	<input type="checkbox"/>
	CU	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes as an Efficient Drug Carrier for Antiviral Activity", <i>Journal of Biological Chemistry</i> (1987) 262(29):13973-13978	<input type="checkbox"/>
	CV	HO, Rodney J.Y., et al. "Target-sensitive Immunoliposomes: Preparation and Characterization", <i>Biochemistry</i> (1986) 25:5500-5506	<input type="checkbox"/>
	CW	ALLEN, T.M., et al. "Large unilamellar liposomes with low uptake into the reticuloendothelial system", <i>FEBS Letters</i> (1987) 223(1):42-46	<input type="checkbox"/>
	CX	KLIBANOV, Alexander L. "Amphipathic polyethyleneglycols effectively prolong the circulation time of liposomes", <i>FEBS Letters</i> (1990) 268(1):235-237	<input type="checkbox"/>
	CY	WOODLE, Martin C., et al. "Sterically stabilized liposomes", <i>Biochimica et Biophysica Acta</i> (1992) 1113:171-199	<input type="checkbox"/>
	CZ	CORNELIE, S., et al. "Methylated cpG-Containing Plasmid Activates the Immune System", <i>Scandinavian Journal of Immunology</i> (2004) 59:143-151	<input type="checkbox"/>
	DA	SASAKI, Shin, et al. "Adjuvant formulations and delivery systems for DNA vaccines", <i>Methods</i> (2003) 31:243-254	<input type="checkbox"/>
	DB	C.J. WHEELER, et al. "A novel cationic lipid greatly enhances plasmid DNA delivery and expression in mouse lung", <i>Proc. Natl. Acad. Sci. USA</i> (1996) 93:11454-11459	<input type="checkbox"/>
	DC	LIU, Y, et al. "Cationic Liposome-mediated intravenous Gene Delivery", <i>J. Biol. Chem.</i> (1995) 270(42):24864-24870	<input type="checkbox"/>
Examiner Signature			Date Considered

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

Substitute for form 1449B/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/780,114
				Filing Date	February 17, 2004
				First Named Inventor	Dow, Steve W.
				Art Unit	1633
				Examiner Name	Anne Marie Sabrina. Wehbe
Sheet	6	of	6	Attorney Docket Number	021819-000130US

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials *	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	DD	ZOU, Yiyu, et al. "Effective Treatment of Early Endobronchial Cancer With Regional Administration of Liposome-p53 Complexes", <i>J. Natl. Cancer. Inst.</i> (1998) 90(15):1130-1137	<input type="checkbox"/>
	DE	OUDRHIRI, Noufissa, et al. "Gene transfer by guanidinium-cholesterol cationic lipids into airway epithelial cells <i>in vitro</i> and <i>in vivo</i> ", <i>Proc. Natl. Acad. Sci. USA</i> (1997) 94:1651-1656	<input type="checkbox"/>
	DF	STRIBLING, Roscoe, et al. "Aerosol gene delivery <i>in vivo</i> ", <i>Proc. natl. Acad. Sci. USA</i> (1992) 89:11277-11281	<input type="checkbox"/>
	DG	NABEL, Gary.J., et al. "Direct gene transfer with DNA-liposome complexes in melanoma: Expression, biologic activity, and lack of toxicity in humans", <i>Proc. Natl. Acad. Sci. USA</i> (1993) 90:11370-11311	<input type="checkbox"/>
	DH	LI, Daqing, et al. "Combination Surgery and Nonviral Interleukin 2 Gene Therapy for Head and Neck Cancer", <i>Clinical Cancer Research</i> (1999) 5:1551-1556	<input type="checkbox"/>
	DI	PHILIP, Ramila, et al. " <i>In Vivo</i> Gene Delivery", <i>J. Biol. Chem.</i> (1993) 268(22):16087-16090	<input type="checkbox"/>
	DJ	HIROAKI, Hemmi, et al. <i>Nature Immunology</i> (2002) 3(2): 196-200	<input type="checkbox"/>
	DK		<input type="checkbox"/>

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.